National Environmental Laboratory **Accreditation** Conference

nelac

Program Policy and Structure

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1.0 PROGRAM POLICY AND STRUCTURE

Chapter One provides an overview of the history, purpose and objectives of the National Environmental Laboratory Accreditation Conference (NELAC). The organizational structure and function of NELAC, and the roles of the various participants, form the major portion of this chapter. In addition, the Constitution and Bylaws, and the content of the five chapters which follow are briefly described. Together, these six chapters and related appendices constitute the NELAC standards.

1.1 INTRODUCTION

1.1.1 Overview of NELAC

This association shall be known as the “National Environmental Laboratory Accreditation Conference” (NELAC) and is sponsored by the United States Environmental Protection Agency (EPA) as a voluntary association of state and federal officials. The purpose of the organization is to foster the generation of environmental laboratory data of known quality in a cost-effective manner through the development of nationally accepted standards for environmental laboratory accreditation. NELAC encompasses all fields of testing associated with compliance with EPA regulations. The program will be administered by state and federal accrediting authorities in a uniform, consistent fashion nationwide.

1.1.2 History

NELAC is the result of a joint effort by EPA, other federal agencies, the states, and the private sector that began in 1990 when EPA’s Environmental Monitoring Management Council (EMMC) established an internal work group to consider the feasibility and advisability of a national environmental laboratory accreditation program. The work group concluded that EPA should consult with representatives of all stakeholders, by establishing a federal advisory committee. As a result, the Committee on National Accreditation of Environmental Laboratories (CNAEL) was chartered in 1991 under the Federal Advisory Committee Act. In its final report to EMMC, CNAEL recommended that a national program for environmental laboratory accreditation be established. In response to the CNAEL recommendations, EPA and state representatives formed the State/EPA Focus Group that developed a proposed framework for NELAC, modeled after the

National Conference on Weights and Measures. The Focus Group prepared a draft Constitution, Bylaws and standards, which were published in the Federal Register in December 1994. NELAC was established on February 16, 1995 by state and federal officials with the adoption of an interim Constitution and Bylaws.

NELAC was established as a standards-setting body, only, to support a National Environmental Laboratory Accreditation Program (NELAP). The goal of NELAP is to foster cooperation with the current accreditation activities of different states or other governmental agencies, through the adoption of NELAC standards, thereby reducing the number of on-site inspections, proficiency tests and related requirements with which the accredited laboratories must comply. It is intended that NELAP function in a manner which will not compromise existing standards of the states and federal agencies and will require minimum outlay of state and federal funds to implement.

1.1.3 Summary of the NELAC standards

The NELAC uniform standards are contained in this chapter and the following five chapters and related appendices.

Chapter 2 contains the criteria for the proficiency testing (PT) program. Laboratory participation in PT programs fulfills one part of the quality assessment requirements of NELAC. The PT programs in which a laboratory must participate to become accredited are defined as well as the criteria for samples, PT providers, and acceptance limits.

Chapter 3 describes the essential elements that are to be included in an on-site assessment and the requirements for an accrediting authority conducting on-site assessments. The qualifications and requirements for assessors are described as well as the program elements to ensure uniform and consistent implementation of the NELAC standards.

Chapter 4 describes the accreditation process the laboratory must follow to be recognized as a NELAC laboratory. The chapter defines the period of accreditation, and the process for maintaining, awarding and revoking accreditation.

Chapter 5 and the related appendices contain the elements of the laboratory quality system. The section provides detail concerning quality assurance/quality control requirements so

that all accrediting authorities will evaluate laboratories consistently and uniformly.

Chapter 6 defines the process and operating requirements established by NELAC for an accrediting authority to become nationally recognized. It provides the policies and criteria that an accrediting authority must meet to apply for and maintain recognition.

1.1.4 General application of NELAC standards

These standards are for use by accrediting authorities and others concerned with the competence of environmental laboratories. Note that any reference to NELAP approval or NELAP accreditation means that the accrediting authority or laboratory meets the requirements in the NELAC standards, and is not endorsement by EPA.

1.1.5 Application of NELAC standards to small laboratory operations

All laboratory operations subject to NELAC standards are expected to generate data of known quality and maintain the quality systems required to generate quality data. However, NELAP recognizes that some laboratory operations have some unique characteristics that differentiate them from other operations. The NELAC standards have addressed these issues by allowing some flexibility in meeting the requirements for personnel (Section 5.4.2, Section 5.6) and their credentials (Section 4.1.1).

1.2 OBJECTIVES

The objectives of NELAC, as specified in Article II of the Constitution, are: to provide a national forum for the discussion of all questions related to standards for environmental laboratory accreditation; to provide a mechanism to establish policy and coordinate activities within NELAC; to develop a consensus on uniform standards for laboratory accreditation, and encourage and promote uniform standards of quality for assessment and accreditation; and to foster cooperation among environmental laboratory accrediting authorities and regulatory officials.

1.3 ELEMENTS

Functional elements of the objectives are:

a) To develop and improve the standards for qualifying as an accredited laboratory, for qualifying as an accrediting authority, and for uniformly implementing the national accreditation program. The standards address the accreditation process; on-site laboratory assessments to review the quality systems; assessor training; proficiency testing; and oversight of accrediting authorities for uniform interpretation of the standards.

b) To designate the States, Territories and Possessions of the United States (hereinafter referred to as States) and federal agencies as the accrediting authorities. These authorities may be the assessor bodies, or may use third parties as assessor bodies to carry out in part or in whole the assessment functions. As accrediting authorities, the States and the federal agencies shall grant accreditation and ensure compliance with NELAC laboratory standards and criteria.

c) To provide for reciprocity among the States and the federal agencies by assuring the consistent application of the national standards. Oversight by NELAP assures uniformity among the various accrediting authorities. The Accrediting Authority Review Board (AARB) provides a balanced review of the program.

d) To develop model language for legislation and regulations which can be adopted by the State legislatures and accrediting authorities.

e) To incorporate, to the extent applicable, ISO 25, ISO 43, and ISO 58. NOTE: A review by the Environmental Laboratory Advisory Board (ELAB), a federal advisory committee, is currently underway on whether to include within NELAC, laboratories complying with Good Laboratory Practices (GLP). GLPs are mandated by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). If GLP laboratories are included in NELAC, the EPA GLP programs and the Organization for Economic and Cooperative Development (OECD) GLP

Principle Technical Standards will be incorporated, to the extent applicable.

1.4 PURPOSE AND SCOPE OF NELAC

1.4.1 Purpose

NELAC shall be a standards-setting body. NELAC shall, through the process described in the Constitution and Bylaws, develop, adopt and publish uniform consensus performance standards on which the national accreditation program shall be based. These standards will be adopted by NELAC at its annual meeting. These uniform standards shall include, but are not limited to, quality systems, proficiency testing, audit programs, and other key elements as established by the standing committees of NELAC. It is not the purpose of NELAC to function as an assessor body, oversee or approve assessor bodies, or administer any of the main elements of the accreditation program, other than the development and adoption of standards.

1.4.2 Scope

The scope of NELAC shall encompass the necessary scientific testing to serve the needs of the States, United States Environmental Protection Agency (EPA), and other federal agencies involved in the generation and use of environmental data, where such generation or use is mandated by EPA statutes and pursuant regulations. Laboratories are encouraged to use the NELAC standards for all other tests.

Applicable EPA statutes include the Clean Air Act (CAA); the Comprehensive Environmental Response Compensation and Liability Act (CERCLA); the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); the Federal Water Pollution Control Act (Clean Water Act; CWA); the Resource Conservation and Recovery Act (RCRA); the Safe Drinking Water Act (SDWA); and the Toxic Substances Control Act (TSCA). The standards shall also include provisions to permit special requirements or fields of testing promulgated by any of the accrediting authorities.

The standards shall not be implemented or administered in a way which limits the ability of local, state or federal agencies to investigate and prosecute enforcement cases. Specifically, when engaged in the collection and analysis of forensic evidence to support litigation, those agencies may use any procedure that is appropriate given the nature of

the investigation, subject only to the bounds of sound scientific practice. The standards shall not apply to governmental laboratories engaged solely in the analysis of forensic evidence.

1.5 NELAC PARTICIPANTS

The participants of NELAC shall be from the States and federal agencies, the organizations subject to accreditation under the standards of NELAC and other interested groups (see Section 1.7.4).

1.6 ROLES AND RESPONSIBILITIES OF THE FEDERAL GOVERNMENT, THE STATES, AND OTHER PARTIES

1.6.1 EPA

EPA shall provide staff support to NELAC as provided for in the Bylaws and agreed to by EPA. EPA shall assist NELAC by providing all proposed and final standards and publishing final standards on the NELAC electronic bulletin board.

EPA also participates in joint activities with other federal and State agencies, as described below.

1.6.1.1 National Environmental Laboratory Accreditation Program

EPA shall establish and administer the National Environmental Laboratory Accreditation Program (NELAP), and shall staff an office to oversee the implementation of NELAC standards. The purpose of this oversight is to ensure a high degree of standardization and coordination among the different accrediting authorities.

NELAP performs the following functions in support of NELAC:

a) evaluating and approving the implementation of NELAC standards by accrediting authorities;

b) establishing and maintaining a national database on environmental laboratories which contains information on the status of accrediting authorities, current status of NELAC accredited laboratories, and status of providers of proficiency test samples;

c) where conflict of interest may occur in an accrediting authority, accrediting that authority's principal laboratories;

d) accrediting EPA laboratories;

e) reporting to NELAC on the evaluation of the conformance of State and federal accreditation program activities to NELAC standards;

f) reporting to NELAC on results of evaluations of proficiency testing sample providers and assessor training programs; and

g) approving supplemental accreditation requirements proposed by accrediting authorities (see Section 1.9.2).

1.6.2 States and Federal Agencies as Accrediting Authorities

In order to be considered a NELAP approved accrediting authority, the individual State or federal program must adopt the NELAC standards, utilize assessors trained according to the requirements of NELAC, and be evaluated by the EPA oversight office as being an agency whose accreditation and assessment program meet all of the requirements of NELAC. Failure in any one of these areas would preclude a State or federal program from being recognized by NELAP.

1.6.2.1 Federal agencies

To operate as accrediting authorities, or to obtain NELAC accreditation for their environmental monitoring laboratories, federal agencies shall conform to the NELAC standards.

1.6.2.2 States

The authority of the States to adopt the NELAC standards is manifest in the authority granted to their administrative agencies by State legislatures. State governments shall be the principal accrediting authorities.

1.6.2.3 Accrediting authorities

An accrediting authority can be either a) any federal agency with responsibility for operating mandated environmental monitoring programs which require laboratory testing, or b) any State which requires laboratory testing in conformance with at least one of the EPA programs listed within the scope of NELAC (see Section 1.4.2). If a State chooses not to participate in the NELAC program, laboratories in that State may obtain accreditation from any other accrediting authority.

A primary accrediting authority is one which ensures directly that the laboratory is in conformance with the NELAC standards. A secondary accrediting authority is one which, through reciprocity, recognizes the accreditation of a primary accrediting authority.

1.6.2.3.1 Responsibilities of primary accrediting authorities

Once a State or federal agency has been approved by NELAP as being an entity whose accreditation and assessment program meets all of the requirements of NELAC, it will be a primary accrediting authority, and it will have full responsibility for:

a) using the NELAC standards as the basis for assessing the qualifications of laboratories applying for initial or continuing NELAC accreditation;

b) ensuring conformance by the laboratories it accredits with the national standards established by NELAC;

c) accrediting applicant laboratory organizations through the review and approval of applications, performance of on-site assessments, evaluation of results on proficiency testing samples, and enforcement of all applicable laws and rules relating to accreditation; and

d) submitting the names and appropriate accreditation material to EPA for inclusion in the national laboratory database.

Federal laboratories within a State may be accredited by the State accrediting authority or by a federal accrediting authority. A State accrediting authority is the primary

accrediting authority for all non-federal NELAP accredited laboratories in that State. However, if the State accrediting authority does not grant NELAP accreditation for testing in conformance with a particular field of testing (see section 1.9), laboratories may obtain primary accreditation for that particular field of testing from any other accrediting authority.

In addition, a primary accrediting authority may delegate assessment activities to a third party body (assessor body). If any of these assessment activities are delegated to a third party, the accrediting authority maintains responsibility for ensuring compliance with the standards established by NELAC.

1.6.2.3.2 Responsibilities of secondary accrediting authorities

A secondary accrediting authority must be approved by NELAP as being an entity whose accreditation and assessment program meets all of the requirements of NELAC for a secondary accrediting authority.

A secondary accrediting authority may require laboratories to submit an application, may issue certificates of accreditation, and will exercise its legal authority for enforcement of all applicable laws and rules. However, it must recognize the laboratory accreditations through reciprocity, and must not replicate any of the assessment functions, of a primary accrediting authority.

1.6.2.3.3 Accreditation fees

Accrediting authorities may adopt and impose laboratory accreditation fees.

1.6.3 Reciprocity

Reciprocity means that an accrediting authority will recognize and accept the accreditation status of a laboratory issued by another NELAP accrediting authority. This principle of reciprocity is an element of the national accreditation standard to which all accrediting authorities are held. In recognizing the accreditation status of a laboratory through reciprocity, the accrediting authority assumes the responsibilities of a secondary accrediting authority as stated in Section 1.6.2.3.2. However, a decision arising from a legal action within the jurisdiction

of a secondary accrediting authority may prevent recognition and acceptance of the primary accreditation.

Reciprocity among the environmental laboratory accreditation authorities is necessary to the success of a national program. The essential ingredient of reciprocity is uniformity from one accrediting authority to another. The mechanisms to assure this uniformity (e.g., uniform national performance standards, thorough and consistent inspections, and comparable decisions on accreditation status when deficiencies are uncovered) are necessary to ensure that reciprocity is equitable.

1.6.4 Joint Federal and State Roles

NELAC shall be the joint responsibility of EPA, the States, and the other federal agencies. As provided in the following section on the structure of NELAC and in the NELAC Bylaws, EPA, the States, and the other federal agencies share responsibilities of governance, analysis and establishment of policy and NELAC technical standards.

1.6.5 Assessor Bodies

An assessor body, operating under written agreement with an accrediting authority, may perform specified functions of the assessment process. These functions may include: the review of the laboratories' documentation regarding facilities, personnel, use of approved methods, and quality assurance procedures; and conduct of on-site assessments, including review of performance in the analysis of proficiency test samples. The assessor body reports directly to the accrediting authority under which it is operating. The assessor body will provide full documentation to the accrediting authority. Only the accrediting authority may determine if a laboratory has met the NELAC standards, may issue certificates of accreditation, may make any decisions on the granting and withdrawal of a laboratory's accreditation status, and may take responsibility for the accreditation process.

1.6.6 Other Parties

All other interested parties including, but not limited to, the laboratory industry, clients of the laboratory industry, environmental or other public interest groups, private industry, third party assessors, and the general public, may participate in NELAC. In this role, these other parties may

bring technical and policy issues to the attention of NELAC, its Board of Directors, or its committees and subcommittees. It is anticipated that these issues shall be brought to NELAC in the form of reports, presentations, discussion material, or other forms of documentation for presentation at the NELAC annual, interim , or committee/subcommittee meetings.

1.7 STRUCTURE OF NELAC

The structure of NELAC is shown in Figure 1-1. NELAC is composed of a Board of Directors, a House of Representatives, a House of Delegates, Contributors, and a number of committees. There are nine elected officials of NELAC: the Chair; the Chair-Elect; the immediate Past Chair; and six members at large. The Standing Committees and Administrative Committees are appointed by the Chair. The activities of the Standing and Administrative Committees are overseen by the Board of Directors.

NELAC will meet twice a year: an annual meeting at which final action is taken on all issues, and an interim meeting about six months prior to the annual meeting at which time committees meet to receive, consider and deliberate on issues, propose and draft standards or policies for adoption at the annual meeting.

NELAC shall also consider advice and comment provided by the Environmental Laboratory Advisory Board (ELAB) chartered under the Federal Advisory Committee Act and the Accrediting Authority Review Board (AARB).

1.7.1 The Board of Directors

The Board of Directors consists of the NELAC Chair, the Chair-Elect, immediate Past Chair, six members elected at large from the active membership (to serve 3-year staggered terms), a NELAC Director, and an Executive Secretary. The NELAP Director is the ex officio Director of NELAC. The Executive Secretary is an EPA employee.

The Board of Directors serves as a policy and coordinating body in matters of national and international significance and makes interim policy decisions when necessary between annual meetings. The Board of Directors has the overall responsibility and authority for the supervisory, administrative and procedural duties associated with NELAC. The Board of Directors will charge the committees with

issues they must address and may suggest other issues for committee consideration. Comments on the standards should be directed to the committees through the chairs.

1.7.2 The Environmental Laboratory Advisory Board

The Environmental Laboratory Advisory Board (ELAB), chartered under the Federal Advisory Committee Act, consists of members appointed by EPA and composed of a balance of non-State, non-federal representatives, from the environmental laboratory community, and co-chaired by an ELAB member and an EPA representative. The ELAB advises EPA and NELAC on matters affecting the interests of the regulated laboratories and other interested parties. The recommendations of the ELAB shall be presented to the Chairs of the standing committees, the Board of Directors and to EPA.

1.7.3 The Accrediting Authority Review Board

The Accrediting Authority Review Board (AARB) is composed of five representatives from EPA, other federal agencies, and the States. The AARB shall include one member from EPA and at least two members from the States. The AARB annually selects one of its members to serve as its chair. All members are appointed by the NELAC Director following consultation with the Board of Directors. Each member shall serve five years with one member appointed annually. The AARB has the responsibility to monitor EPA to assure that EPA is following the NELAC standards for approving the accrediting authorities, and to serve as an appeal board for accrediting authorities that have been denied NELAP recognition or have had such recognition revoked (see Chapter 6). In all cases, the final decision remains with the NELAP Director. The AARB will report on its activities to the Board of Directors at each annual meeting.

1.7.4 The Participants

The participants consist of two groups, i.e., Voting Members and Contributors.

Membership is limited to officials who are in the employ of the Government of the United States and the States, and who are actively engaged in environmental programs or accreditation of environmental laboratories. State and federal participants being compensated by the private sector to inspect environmental laboratories or as consultants are

considered to have a conflict of interest and are ineligible for Voting Membership but may participate as Contributors. The Voting Member may vote and is eligible to serve on all committees and the Board of Directors. At the annual meeting the Voting Members are divided into a House of Representatives and a House of Delegates.

The House of Representatives is composed of one officially designated representative from each State, one representative from each of eight EPA Assistant/Associate Administrators, and one representative from each EPA Region. Each other cabinet level federal department or independent agency (as defined in the Constitution) with environmental laboratory accreditation, certification or evaluation activities may appoint one official to the House of Representatives.

The House of Delegates is composed of all other State and federal environmental officials. The size of the House of Delegates is not limited.

Contributors are all other interested parties and groups. They include, but are not limited to, laboratory personnel, industry representatives, environmental groups, the general public, laboratory associations, industry associations, accreditation associations and retired Voting Members. The Contributors may not vote, but can make presentations, comments or input at all stages of the standards and procedures making process, and do have the ability to enter the substantive debate on the floor of the meeting as it occurs. Contributors are eligible to serve as non-voting participants on all committees.

1.7.4.1 Participation of the Voting Members and Contributors

Contributors, as well as Voting Members, have the right to appear before the standing committees as they consider proposed standards and procedures related to the national accreditation program and to debate the substantive issues before NELAC as such discussion occurs during the meeting. Appearance before the committees will be in accordance with procedures approved by the Board of Directors and Voting Membership.

1.7.5 The Committees

Two types of committee are associated with NELAC: Standing Committees and Administrative Committees. Each committee has five Voting Members including the chair and five Contributors who may not vote. Except for the Nominating Committee, the Voting Members of each committee annually select a chair from one of its Voting Members. All committees report to NELAC through the Board of Directors. Following each annual meeting, the Board of Directors will make available an updated roster of the Board of Directors, NELAC officers and committee participants and chairs.

1.7.5.1 The Standing Committees

The participants of each committee serve for five years, with one Voting Member and one Contributor being appointed each year. There are seven Standing Committees:

- Program Policy and Structure Committee
- Accrediting Authority Committee
- Quality Systems Committee
- Proficiency Testing Committee
- On-site Assessment Committee
- Accreditation Process Committee
- Implementation Committee

The Standing Committees shall receive input regarding standards and test procedures, then process this input into resolutions which shall be put before the Voting Membership at the annual meeting. These resolutions will be made available not less than 30 days prior to the annual meeting. All resolutions shall be presented to the Voting Membership at the annual meeting for discussion and ballot. The committees may also receive input via comments and presentations at the interim and annual meetings. The committees shall draft resolutions which shall be made available not later than 30 days prior to either the interim or annual meetings. The committees shall prepare and arrange agenda items for interim meetings and annual meetings to be made available 30 days prior to the meeting.

1.7.5.1.1 Program Policy and Structure Committee

This committee generates the Constitution and Bylaws of NELAC, and interprets the intent and meaning of the Constitution and Bylaws, presents amendments, proposes changes in organizational structure, and defines roles and

responsibilities as appropriate, for approval of the Voting Membership. This committee develops modifications to the scope, structure, and requirements to the tiers and fields of testing.

1.7.5.1.2 Accrediting Authority Committee

This committee develops the standards for use by EPA to oversee compliance by State and federal accrediting authorities with NELAC standards. This committee considers matters concerning implementation of reciprocity among accrediting authorities.

1.7.5.1.3 Quality Systems Committee

This committee develops and keeps current uniform standards for quality systems in testing operations. The elements of the quality system include organizational structure, responsibilities, procedures, processes and resources (e.g., facilities, staff, equipment) for implementing quality management in testing operations.

1.7.5.1.4 Proficiency Testing Committee

This committee develops standards for the proficiency testing samples, develops criteria for selection of the providers of the samples, and develops and updates protocols for the use of proficiency test samples and data in the accreditation of laboratories.

1.7.5.1.5 On-Site Assessment Committee

This committee generates procedures for the on-site assessments, and publishes standard check lists based on these procedures. This committee also establishes the frequency of inspection, and the minimum education, experience, and training requirements of the assessors.

1.7.5.1.6 Accreditation Process Committee

This committee generates and develops procedures for the administrative aspects of the accreditation process of environmental laboratories, for use by the accrediting authorities, including the requirements for accreditation, procedures for changes in accreditation status, roles and responsibilities of laboratories, and appeal processes.

1.7.5.1.7 Implementation Committee

This committee provides the Standing Committees with current information on regulations and laws that impact laboratory testing and accreditation. The Implementation Committee is also responsible for the development of model language for state legislation and regulations that reflect the findings and actions of NELAC.

1.7.5.2 The Administrative Committees

Administrative Committees have varying terms. The duties are outlined below. The term of service shall be three years; two Voting Members and two Contributors will be appointed each of two years and one Voting Member and one Contributor the third year, except for the Nominating Committee (see below).

1.7.5.2.1 Conference Management Committee

This committee recommends to the Board of Directors the places and dates of each annual and interim meeting of NELAC; and advises and assists the Executive Secretary with the logistic details of the interim and annual meetings and with preparing publications for the Annual and interim meetings.

1.7.5.2.2 Nominating Committee

The chair is the NELAC Past Chair. Four Voting Members and five Contributors shall be appointed annually to serve one year. This committee presents nominees for all elective offices at the annual meeting. The names of these nominees shall appear in the report of the Nominating Committee and be published in the meeting announcement.

1.7.5.2.3 Membership and Outreach Committee

This committee initiates membership invitations and maintains an active roster, publicizes NELAC to prospective participants, coordinates and resolves participants' concerns, and establishes criteria and verifies the credentials of Voting Members.

This committee solicits and develops informational materials to promote understanding and appreciation of the importance of consistent standards for environmental sampling and

analysis in fostering quality data on which to base responsible public and environmental health decisions.

This committee promotes a spirit of cooperation and timely dialogue between NELAC and other organizations and federal agencies.

1.8 CONDUCT OF CONFERENCE BUSINESS

1.8.1 The Generation of Standards

The process for the generation and adoption of standards by a State accrediting authority is shown in Figure 1-2. The standards for the accreditation of laboratories begin with recommendations made within or to the committees. Committees shall propose standards in the form of resolutions on which the Voting Membership shall vote. Standards proposed by the committees are publicized on the NELAC electronic bulletin board by EPA not later than 30 days prior to the date of the meeting at which they will be considered.

Proposed amendments from the floor to specific standards and proposals offered by the committee for adoption by NELAC shall be allowed in the manner described in the Constitution and Bylaws. Amendments to the report describing committee activities over the year will not be allowed without the concurrence of the chairman of the subject committee and the concurrence of the Chair of NELAC.

EPA shall publish the final standards.

1.8.2 Meetings

1.8.2.1 Annual Meeting

An annual meeting of NELAC shall be held to conduct business including, but not limited to, election of officers, consideration of issues for presentation to the membership for voting, receiving reports from committees, task groups, or other sources, and conducting other business of NELAC. All final action on resolutions or proposals shall take place at the annual meeting.

The Board of Directors shall determine the place and dates for the annual meeting, after receiving recommendations from the Conference Management Committee, and shall publish this information on the NELAC electronic bulletin board at least 90 days prior to the annual meeting.

A completed registration for the annual meeting shall serve as the application for participation as Voting Member or Contributor. The registration form must be completed by all potential participants, whether or not attending the annual meeting. Prior to the annual meeting, the Executive Secretary shall certify the names of the Voting Members and their alternates of the House of Representatives to the Board of Directors. The Nominating Committee shall present, to the Board of Directors, nominees for all elective offices for the annual meeting. The names and qualifications of the nominees shall be published in the annual meeting announcement.

The following deadlines will apply in preparing and submitting material for the annual meeting:

a) Sixty days prior to the date of the annual meeting, each of the standing committees shall present to the Board of Directors a summary of the issues and matters considered by the committees over the course of the year. This report shall discuss all matters which the committee considered since its last report, including how the committee disposed of the issues it considered. The report shall also contain draft standards for consideration by NELAC.

b) Committees shall prepare and arrange agenda items and resolutions for the annual meeting. These, and other resolutions received by the Board of Directors will be made available not less than 30 days prior to the meeting.

c) Standards proposed by the committees for consideration at the annual meeting shall be publicized on the electronic bulletin board not less than 30 days prior to the annual meeting.

Within 90 days following the annual meeting, the Board of Directors shall make available an updated roster of the Board of Directors, NELAC officers, committee members and chairs, and minutes and findings of the meeting to the participants. EPA shall publish the final standards within 90 days following the annual meeting. Changes in organization and/or procedures of NELAC proposed at the annual meeting shall not be acted upon until the annual meeting following the annual meeting at which proposed.

1.8.2.2 Interim Meeting

The interim meeting, at which time committees meet to receive, consider and debate on issues, and propose and draft standards or policies for the annual meeting, shall be scheduled approximately six months prior to the annual meeting.

The Board of Directors shall determine the place and dates for the interim meeting, after receiving recommendations from the Conference Management Committee, and shall publish this information on the NELAC electronic bulletin board at least 90 days prior to the interim meeting.

Committees shall prepare and arrange agenda items for the interim meeting. The agenda shall be approved by the Board of Directors and will be made available not less than 30 days prior to the date of the meeting.

Conclusions and findings of the interim meeting shall be provided to the participants not later than 90 days following the interim meeting.

1.8.2.3 Special Meetings

The NELAC Chair is authorized to call a meeting of the Board of Directors at any time deemed necessary by the Chair to be in the best interests of NELAC. Announcements of the meetings and meeting summaries or reports shall be made available to the participants.

1.8.2.4 Committee Meetings

Committees of NELAC are authorized to hold meetings at times other than the annual or interim meeting. Announcements of the meetings and meeting summaries or reports shall be made available to the participants.

1.9 ORGANIZATION OF THE ACCREDITATION REQUIREMENTS

1.9.1 Scope of Accreditation

Laboratories must meet all relevant EPA program requirements, including quality assurance/quality control, use of specified methods, and other criteria.

The accreditation requirements shall be based on the tiered approach shown in Figure 1-3. Laboratories must meet the

general requirements found in Chapter 5, and the specific quality control requirements for the type of testing being performed, as found in Appendix D of Chapter 5. Accreditation will then be granted for compliance with the relevant EPA program, the methods used by the laboratory, and for individual analytes determined by a particular method; e.g., a laboratory determining lead in drinking water, in compliance with the Safe Drinking water Act, by both inductively-coupled plasma mass spectrometry and graphite furnace atomic absorption spectrometry would be accredited for lead by both methods. Loss of accreditation for an analyte would not automatically result in loss of accreditation for all other analytes accredited under the method, provided the laboratory remained proficient in the determination of the other analytes.

The following example shows the tiered approach applied to a laboratory seeking accreditation in hazardous waste organic testing under the auspices of RCRA. The laboratory must meet all the requirements listed in general laboratory (NELAC Chapter 5), chemistry (NELAC Chapter 5, Appendix D.1), the RCRA regulations (40CFR261), and the method(s) used (e.g., SW846 5030/8240). In all cases, a NELAC accredited laboratory must be accredited for the specific method it uses. In some cases the regulations mandate the method to be used (e.g., 40CFR261 specifies SW846 Method 1311, TCLP). In other cases the regulations provide guidance for the methods which can be used (e.g., 40CFR264, Appendix IX, suggests applicable methods). Finally, in some situations the regulations provide no guidance as to the methods to be used (e.g., 40CFR268 lists analytes required to be measured, with no guidance on methods). In those cases where the test method is not mandated by regulation, the laboratory must be accredited for the specific method used, as documented in the laboratory's SOP (see Chapter 5). This method must meet the relevant start-up, calibration, and on-going validation and QC requirements specified in Chapter 5. The tiered approach allows for the incorporation of performance based measurement systems (PBMS) by substituting PBMS for the specified analytical methods when allowed under EPA regulations.

The tiered approach eliminates redundancy by allowing for the incorporation of new methods or new instrumentation without the laboratories repeatedly demonstrating the basic requirements. This structure defines the scope of accreditation for inclusion on the laboratory accreditation certificate. The on-site assessment, proficiency testing

evaluation, and data assessments are the processes for assessing the capabilities of the laboratories within the tiered structure. These processes, defined in Chapters 2 and 3, do not necessarily evaluate all tiers within the tiered structure; e.g., proficiency testing examines the determination of individual analytes in specific matrix types, and is not method-specific. However, they are comprehensive enough to assure the accrediting authority that a system is in place that produces data of known and documented quality.

An accrediting authority may approve a laboratory's application to add an analyte or method to its scope of accreditation by performing a data review without an on-site assessment. An addition to the scope of accreditation via a data review of proficiency testing performance (if available), QC performance and written SOP is at the discretion of the accrediting authority. An addition of a new technology or test method requiring specific equipment may require an on-site assessment.

1.9.2 Supplemental Accreditation Requirements

In addition, a category of supplemental accreditation requirements is designated for additional methods or analytes required by an accrediting authority. Supplemental accreditation requirements shall be reserved for methods or analytes that are not required under any of the EPA programs that are part of NELAC, and shall not be used to modify any NELAC standards for analytes or methods. Any supplemental accreditation requirements essential to meet the specific needs of an accrediting authority would be added at the method-specific or analyte level, and must be approved by NELAP and made available to all NELAC participants. Exceptions to this requirement may be necessary (e.g., national security concerns) and will be processed as waivers by the AARB.

1.9.3 General Laboratory Requirements

The general requirements are applicable to all laboratory applicants regardless of their size, volume of business, or field of testing. The organizational structure, or procedures used by applicant laboratory organizations to meet these general requirements may differ as a function of size or scope of testing of an organization. Under the tiered approach the general requirements shall include the elements outlined in Chapter 5.

The following applicable requirements are presented in Chapter 5 (Quality Systems): Organization and Management (5.4); Quality System - Establishment, Audits, Essential Quality Controls and Data verification (5.5); Personnel (5.6); Physical Facilities - Accommodation and Environment (5.7); Equipment and Reference Materials (5.8); Measurement Traceability and Calibration (5.9); Test Methods and Standard Operating procedures (5.10); Sample Handling, Sample Acceptance Policy and Sample Receipt (5.11); Records (5.12); Laboratory Report Format and Contents (5.13); Subcontracting Analytical Samples (5.14); Outside Support Services and Supplies (5.15); and Complaints (5.16).

1.9.4 General Field Sampling Requirements

(To be developed)

1.9.5 Chemistry Requirements

The following applicable requirements are presented in Section D.1 of Appendix D of Chapter 5 (Quality Systems): Positive and Negative Controls (D.1.1); Analytical Variability/Reproducibility (D.1.2); Method Evaluation (D.1.3); Sensitivity (D.1.4); Data reduction (D.1.5); Quality of Standards and Reagents (D.1.6); Selectivity (D.1.7); and Constant and Consistent Test Conditions (D.1.8).

1.9.6 Whole Effluent Toxicity Requirements

The following applicable requirements are presented in Section D.2 of Appendix D of Chapter 5 (Quality Systems): Positive and Negative Controls (D.2.1); Variability and/or Reproducibility (D.2.2); Accuracy (D.2.3); Test Sensitivity (D.2.4); Selection of Appropriate Statistical Analysis Methods (D.2.5); Selection and Use of Reagents and Standards (D.2.6); Selectivity (D.2.7); and Constant and Consistent Test Conditions (D.2.8).

1.9.7 Microbiology Requirements

The following applicable requirements are presented in Section D.3 of Appendix D of Chapter 5 (Quality Systems): Positive and Negative Controls (D.3.1); Test Variability/Reproducibility (D.3.2); Method Evaluation (D.3.3); Test Performance (D.3.4); Data Reduction (D.3.5); Quality of Standards, Reagents and Media (D.3.6);

Selectivity (D.3.7); and Constant and Consistent test Conditions (D.3.8).

1.9.8 Radiochemistry Requirements

The following applicable requirements are presented in Section D.4 of Appendix D of Chapter 5 (Quality Systems); Positive and Negative Controls (D.4.1); Laboratory Variability/Reproducibility D.4.2); Method Evaluation (D.4.3); Sensitivity (D.4.4); Data Reduction (D.4.5); Quality of Standards and Reagents (D.4.6); Selectivity (D.4.7); and Constant and Consistent Test Conditions (D.4.8).

1.9.9 Microscopy Requirements

(To be developed)

1.9.10 Field Measurement Requirements

(To be developed)

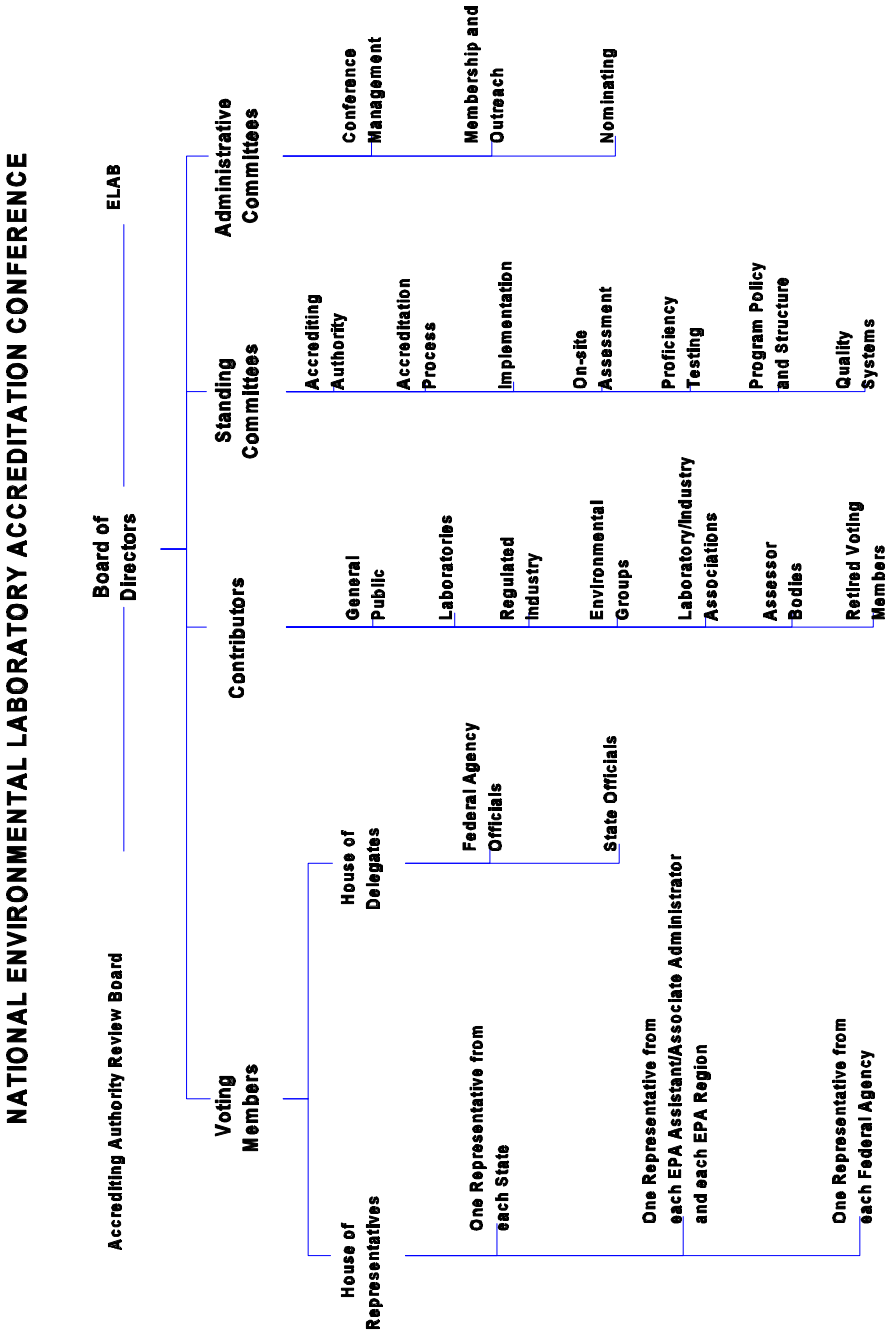


Figure 1-1. NELAC Structure

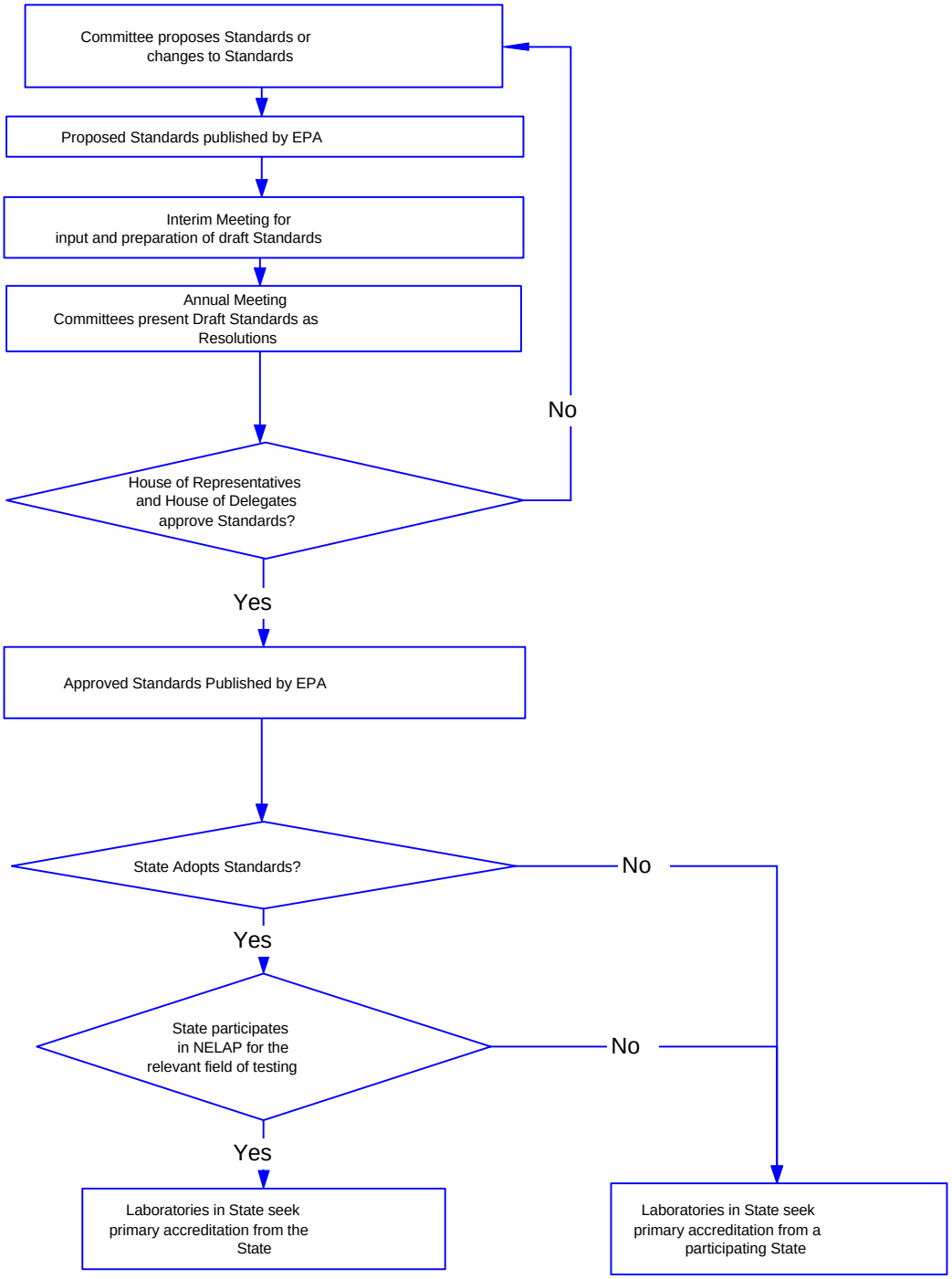
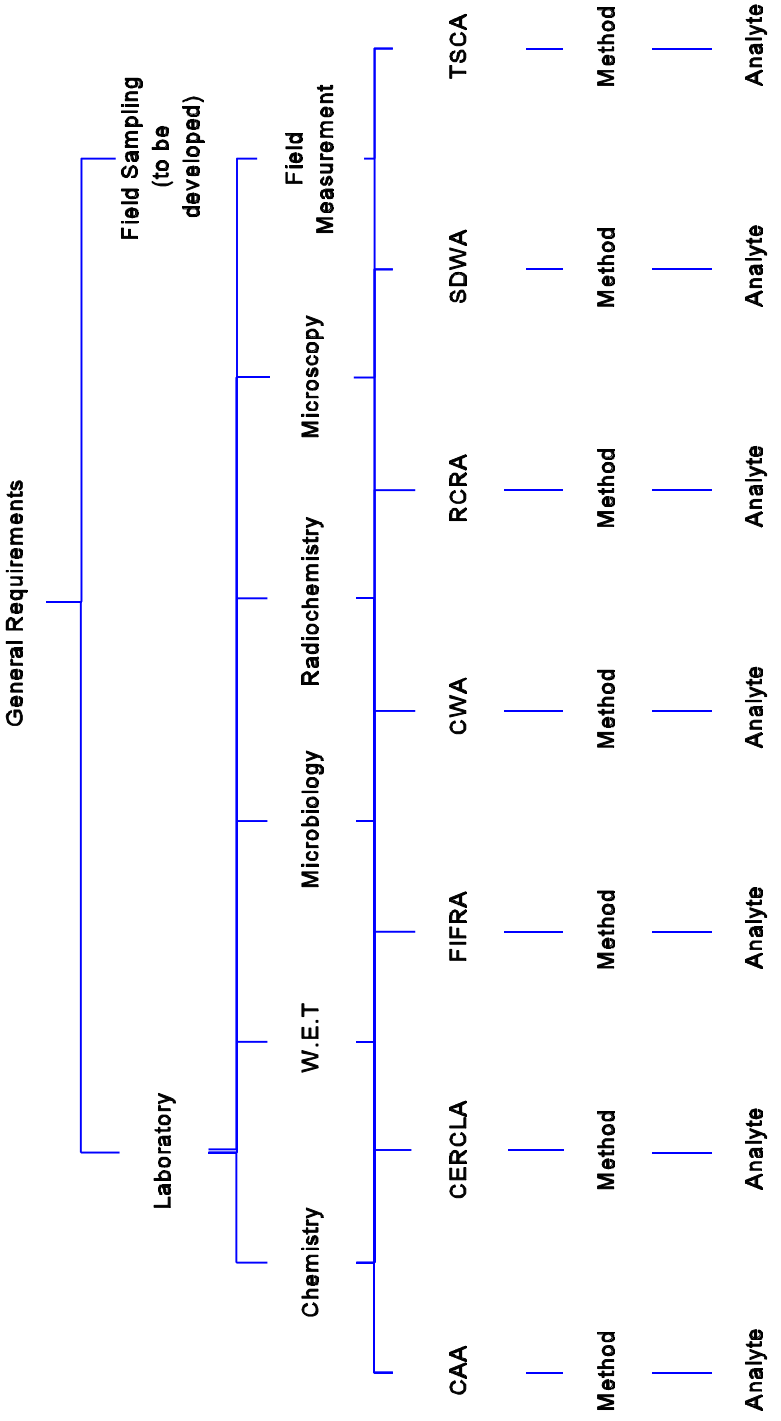


Figure 1-2. Flowchart for Standards Development and Implementation



This figure and the supporting text will be reviewed at a later date to accomodate the unique characteristics of the GLP program, taking into consideration the recommendations of the Environmental Laboratory Advisory Board.

Figure 1-3. NELAC Tiered Scope of Accreditation